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SECTION 6 - SUMMARY OF SAFETY AND EFFECTIVENESS

K023431

(Premarket Notification [510(k)] Number)

1. Applicant

Cardiosonix Ltd.
Beit Milenium
3 Hatidhar Str.
Rananna, 43654 ISRAEL
Tel: +972-9-7766444
Fax: +972-9-7766445

Corresponding Official:

Name: Ahava M. Stein, Consultant
Address: A. Stein - Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as St.
44425 Kfar Saba
ISRAEL
Tel: +972-9-767 0002
Fax: +972-9-766 8534

2. Device Name

Device trade/proprietary name: Quantix/ND Device

Common Name: Blood Flowmeter

Classification Name: Cardiovascular Blood Flowmeter, Class II, 870.2100

3. Predicate Devices

The Quantix/ND device is substantially equivalent to the following device:

Device	Manufacturer	510(k) No.
FlowGuard	Biosonix Ltd.	K013803

4. Intended Use

The Quantix/ND device is intended for non-invasive, peripheral vessel examinations of blood flow measurements

5. Description of the Device

The Quantix/ND is a dual-beam, angle-independent, pulse-wave Doppler ultrasound system used for non-invasive (peripheral vessel) volume blood flow measurements, including blood flow velocity and volume blood flow. In addition to the conventional Doppler (blood flow velocity) measurements, the Quantix/ND technology utilizes special applications of ultrasound Doppler methods to obtain real-time measurements according to the definition of volume blood flow in target blood vessels. By definition, blood flow is the product of velocity and cross-sectional area. In other words, the volume blood flow is calculated by deriving flow velocity from the Doppler shift frequency using the basic standard formula and then multiplying the velocity by the cross-section area of the blood vessel.

6. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the Quantix/ND device are substantially equivalent to the predicate device cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Cardiosonix Ltd.
c/o Mr. Ahava M. Stein
A Stein – Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as St.
44425 Kfar Saba
ISRAEL

Re: K023431
Quantix/ND Device
Regulation Number: 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: II (two)
Product Code: 74 DPW
Dated: October 1, 2002
Received: October 15, 2002

Dear Mr. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

510(k) No.: K018303

Intended Use: Diagnostic Blood Flow Measurements

Transducer: Round pen-probe, 4 MHz, 4 mmϕ

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				P						
Laparoscopic										
Musculo-Skeletal Conventional										
Muscolo-Skeletal Superficial										
Other (Specify)										

N= New Indication; **P = Previously cleared by FDA**; E = Added under Appendix E

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices

510(k) Number K023431

11/12/02

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

510(k) No.: K018303

Intended Use: Diagnostic Blood Flow Measurements

Transducer: Elliptic pen-probe, 4 MHz, 6 mmϕ

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative **(Specify)**										
Intra-operative Neurological										
Pediatric										
Small Organ **(Specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				**E**						
Laparoscopic										
Musculo-Skeletal Conventional										
Muscolo-Skeletal Superficial										
Other (Specify)										

N= New Indication; **P = Previously cleared by FDA**; E = Added under Appendix E

Additional Comments:_____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices

510(k) Number K023931

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